



## HIV and TB : Two Diseases – One Patient

HIV/AIDS Conference, Rome, Italy December 20 2006

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*Lilly*  
Answers That Matter.

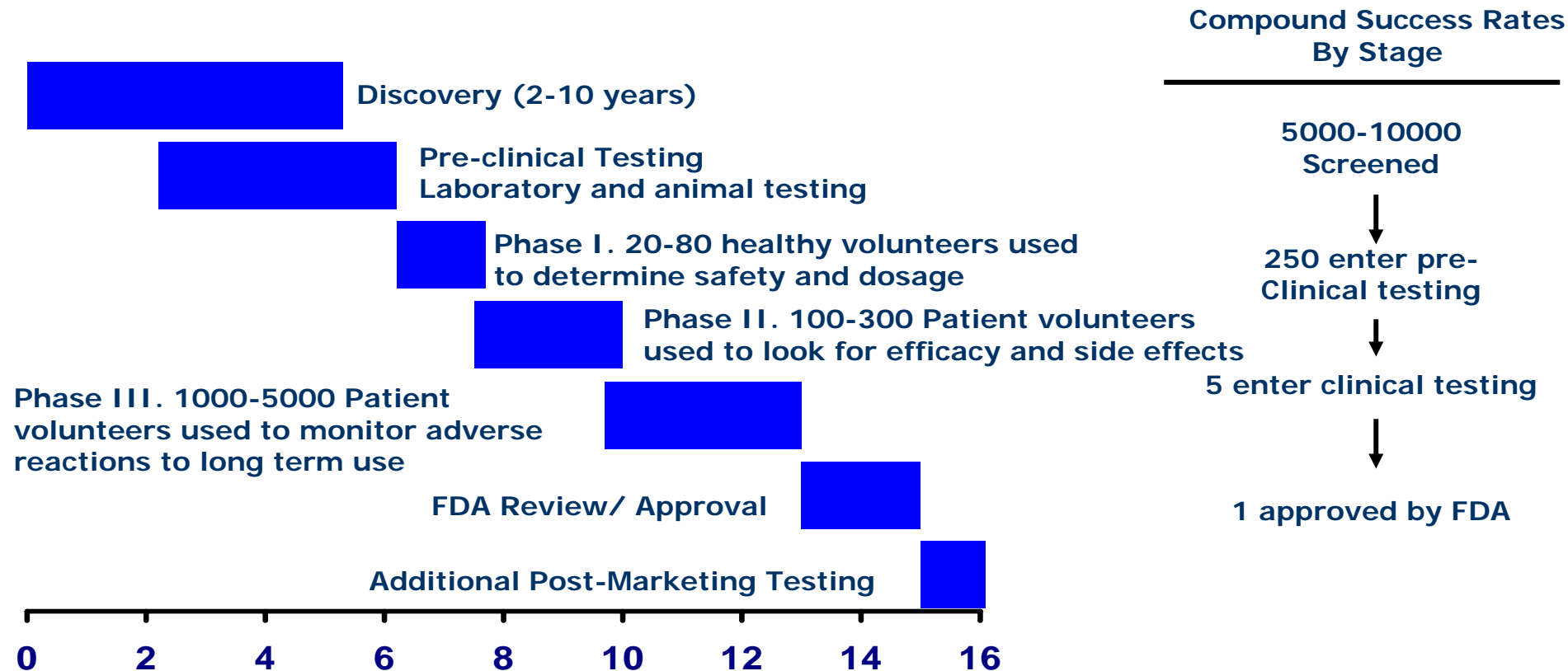
# Leading causes of death - estimates for the year 2002

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Death rates for all causes: 57 million in 2002

Ranked by importance	Cause	% of deaths in the world
1.	Ischemic heart disease	12.6
2.	Cerebrovascular disease	9.7
3.	Lower respiratory infections	6.8
4.	<b>HIV/AIDS</b>	4.9
5.	Chronic obstructive pulmonary disease	4.8
6.	Perinatal conditions	4.3
7.	Diarrhea diseases	3.2
8.	<b>Tuberculosis</b>	2.7
9.	Trachea/bronchus/ lung cancers	2.2
10.	Road traffic accidents	2.1

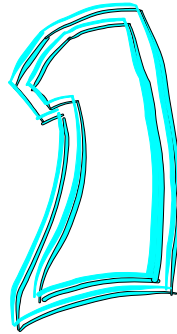
# Finding solutions for leading health problems requires time and resources



# Research & Development Challenges

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As many as 10,000 compounds must be screened to eventually find



**One**

that becomes an approved drug.  
Research and development expenditures pay for the work on the other 9,999 too.

# From Laboratory to Patient

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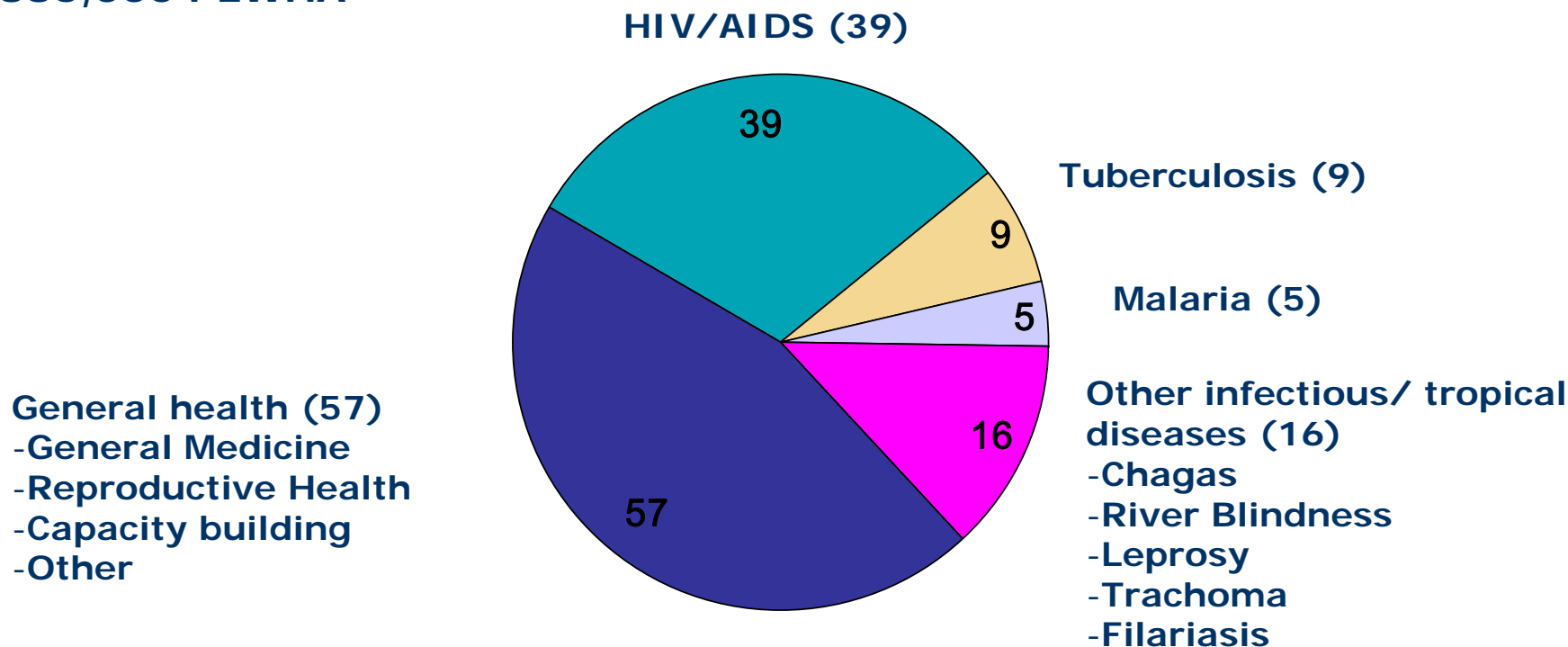
**It takes patience, money and dedication for the long trip from the laboratory bench to the medicine chest. But it is a journey well worth the time and expenses, because it saves and improves millions of lives**

**But**

**Drugs are not enough to save lives. If the health care system and environment (i.e. sanitation, nutrition) are not adequate, impact on health is not optimal**

# Industry contribution to Millennium Development Goals since 2000\*

- 540 million health interventions (enough to reach 2/3 of Sub-Saharan Africa)
- Financial contribution conservatively valued at US\$ 4.38 billion
- AAI (a 7 companies and 5 UN partners initiative) reached more than 886,000 PLWHA



# Pharma Industry Commitment

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- 25 years into HIV/AIDS pandemic
- 20+ ARVs produced so far have converted HIV/AIDS into a manageable chronic condition
- Industry continues R&D to produce new ARVs (e.g. next generation Protease Inhibitors and Fusion Inhibitors)
- 77 medicines and vaccines in development to treat HIV/AIDS and related conditions

Industry recognizes barriers prevent many from accessing innovative ARVs: funding, infrastructure, human resources

# HIV/AIDS: Accelerating Access Initiative (AAI) Impact

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- Accelerating Access Initiative (AAI) brings together 7 companies working on ARVs and 5 UN agencies to expand access to ARVs
- 886,000 HIV patients currently receiving at least 1 ARV medicine provided by AAI companies.
- Pediatric formulations available now in developing countries at preferential prices

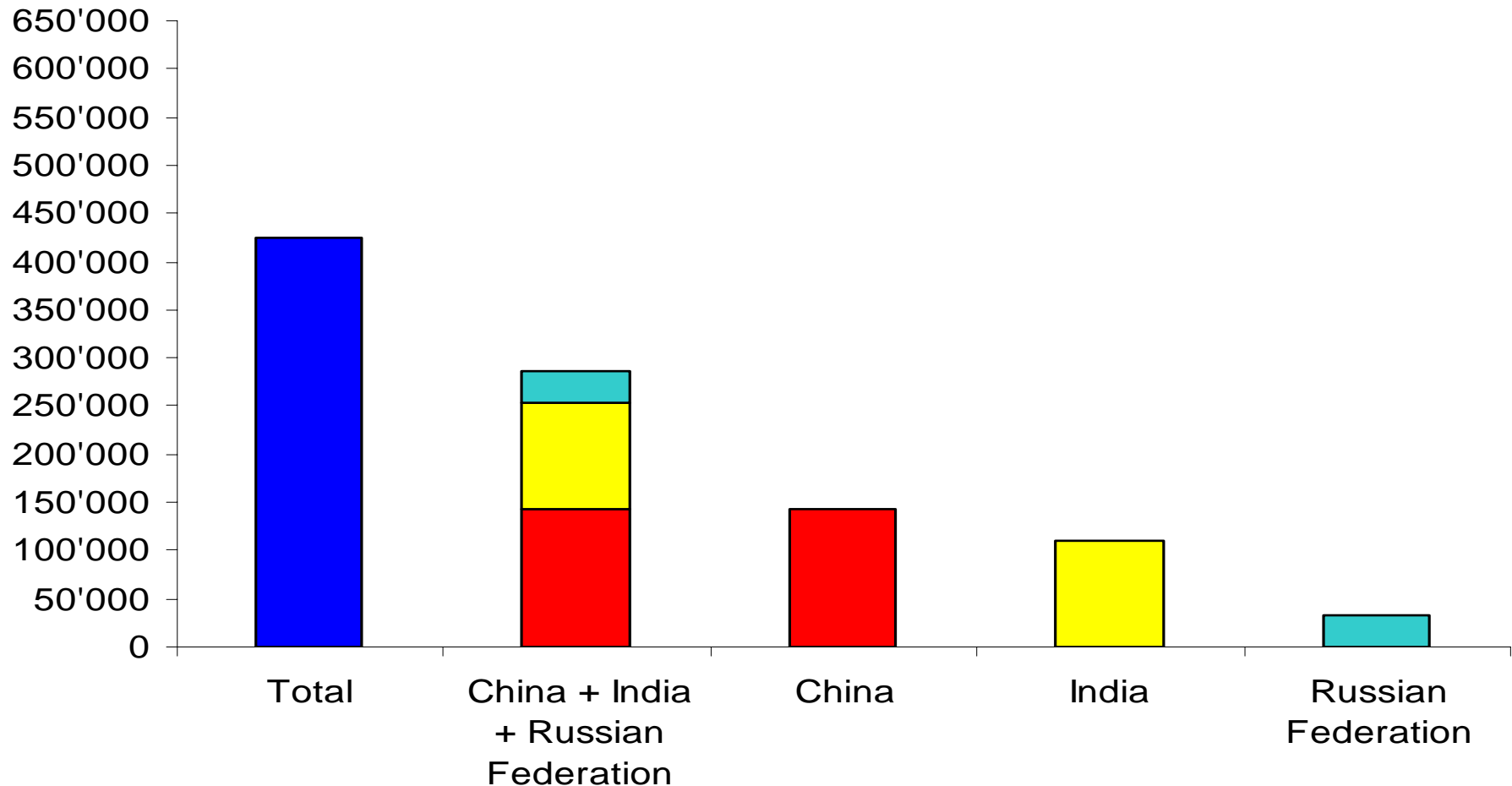


# HIV/AIDS and TB: a lethal synergy

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- HIV, TB, and Malaria, account for over 10% of global deaths per year
  - HIV/AIDS - 3 million
  - TB - 2 million
  - Malaria - 1 million
  - TB leading cause of death in HIV positive people
- 12 million people worldwide are co-infected with HIV & TB (1/3 of PLWHA)
- Half of all HIV patients in sub-Saharan Africa develop active TB
- Multidrug-Resistant Tuberculosis (MDR-TB)
  - Of nearly 9 million new cases of TB each year, 400,000 are MDR-TB
  - Caused by incomplete or incorrect treatment of regular TB.
  - XDR-TB on the horizon.

# Estimated incidence of MDR-TB (2003)\*



# MDR-TB Facts

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- TB kills 2 million people every year (5,000 every day), mostly adults between **15 and 54**.
- 2 billion people are infected with TB worldwide - **1/3** of the world's population.
- China & India account for **50%** of MDR-TB cases.
- TB leads to a decline in productivity estimated at **US\$12 billion** annually.

**Business, Communities & Countries All Lose**

# MDR-TB Challenge

- The required prolonged and more expensive treatment results in poor patient compliance and development of resistance ; thus the need for intensive directly observed treatments (DOTS Plus)



## Lilly's Response to MDR-TB

- Work with public/private partners, health professionals, businesses and communities to address multi-faceted aspects of MDR-TB
- US\$70 million multi-faceted and proactive program
- Lilly serves as catalyst to bring partners together: pioneer and leader in the field

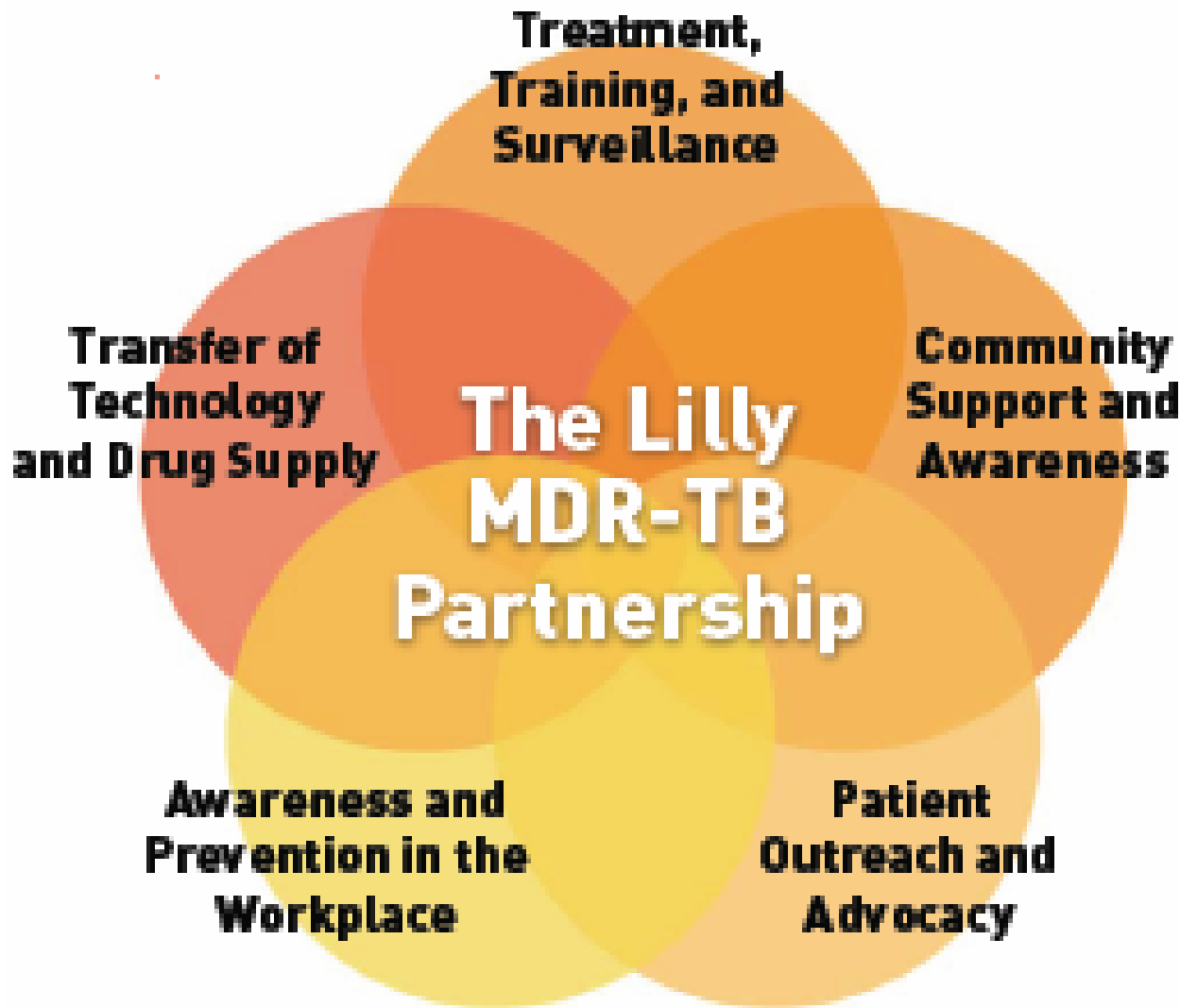
# Answering the public health community call

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- In 2003 Lilly decided to develop a comprehensive initiative encompassing
  - Transfer of Technology
  - Drug Supply at concessionary prices
  - Training tools for health care professionals/training of trainers
  - Involving communities and businesses in improving MDR-TB prevention and treatment adherence
  - Assistance to governments to design sound MDR-TB (DOTS-Plus) strategies
  - Strengthen surveillance systems to understand and handle drug resistance

***VISION:*** to combat the growing MDR-TB pandemic and support the Global Plan to STOP TB and the WHO goal of treating ***800,000 patients by 2015***

# The Lilly MDR-TB Partnership



*Reaching Patients throughout the world*

# Transfer of Technology & Drug Supply



- Share all Lilly's specific and general manufacturing knowledge.
- Create self-sustaining centers of manufacturing excellence capable of providing additional products and employment.
- Support reliable generic producers to ensure an expanded multi-source availability of the two drugs.
- Offer manufacturing firms in MDR-TB "**hot spots**" the technology to produce *capreomycin* and *cycloserine* and provide training in GMPs and Good Business Practices.
- Provide **10 full-time Lilly staff on-site over 4 years** for technical assistance/training.
- Facilities in **China** and **India** will receive technology to produce *capreomycin* and *cycloserine* API's respectively, and **South Africa** and **Russia** will produce both products.

# Training, Treatment & Surveillance

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## World Health Organization

- Provide **technical support** and monitor **drug resistance** to first-line TB drugs.
- Oversee **product distribution** to GLC-approved projects.

## Centers for Disease Control

- Support a **drug surveillance program** for MDR-TB in Russian cities.
- Train local staff in surveillance and laboratory information management.

## Partners in Health/Brigham & Women's Hospital

- Establish a Center of Excellence in Russia for **training** healthcare workers (prison and civilian staff)
- Support Russian Public Health Managers to participate in a **Clinical Effectiveness Program** at Harvard University.



# Training, Treatment & Surveillance

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## International Council of Nurses

- Develop TB & MDR-TB clinical **guidelines for nurses** and curriculum for Nursing School.
- Disseminate guidelines through local ICN members and carry out training activities in high-burden MDR-TB countries.

## World Medical Association

- Develop **distance learning course** for physicians addressing the clinical aspects of MDR-TB.
- Conduct in-country training with local medical associations.

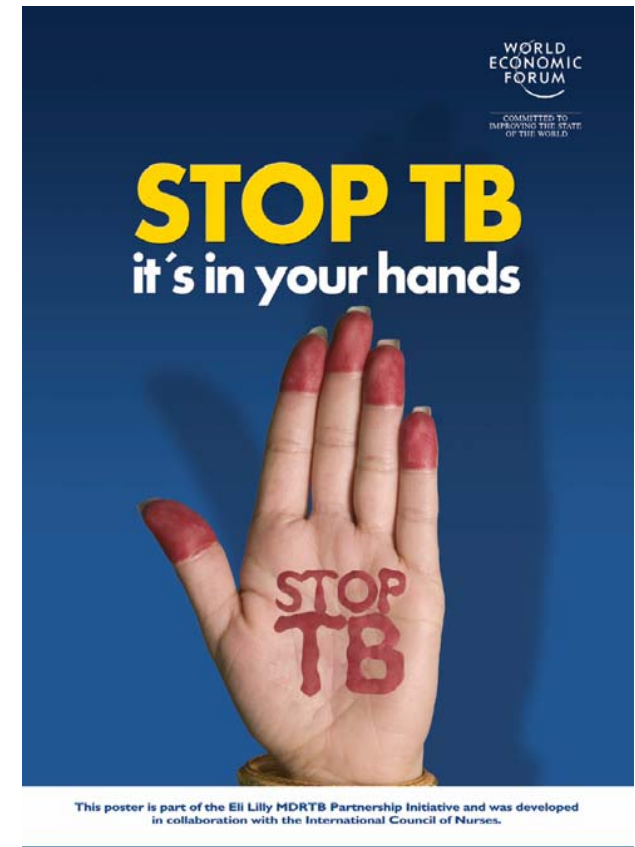
## International Hospital Federation

- Develop TB and MDR-TB **training and distance learning course for hospital managers**.
- Provide in-country training in selected hospital settings.

# Awareness and Prevention in the Workplace

## World Economic Forum

- Develop a **Global Awareness Toolkit for Tuberculosis/MDR-TB in the Workplace** and disseminate through WEF member companies
- Provide **educational material** targeting employees and in-plant health care staff.
- Pilot tested in **India** and adaptation for other high-burden countries with large business communities



# Community Support and Patient Advocacy

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## International Federation of the Red Cross & Red Crescent Societies

- Community support to MDR-TB patients to ensure better access to care and improved compliance
- Educational programs to improve **community awareness** of preventative measures and stigma reduction

## TB Survival Project and TB Alert

- **Patient-led initiative** to raise awareness and engage patients and their families worldwide
- Aims to provide patients with one-to-one **mentoring** and **emotional support**

# Global Partners - Local Action



# Lilly's Impact

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- From 2000 to 2006, Lilly supplied approximately **one million vials** of capreomycin and **5 million capsules** of cycloserine through the WHO's DOTS-Plus program in **40 GLC-approved countries**.
- Lilly's transfer of technology will ensure a **greater supply** of affordable, quality, second-line drugs where they are needed most.
- Lilly and its partners have played vital roles in **influencing key MDR-TB policies** around the world and ensuring their implementation.
- These policies involve the introduction of **new treatment protocols**, and convincing the global health community that treating MDR-TB is just as important as treating primary TB.